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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,268

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XY-lowPressure-USNP

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EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,268	Applicant(s) SCHENK ET AL.	
	Examiner MARCIA S. NOBLE	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,31,39-52 and 62-72 is/are pending in the application.
- 4a) Of the above claim(s) 41-52 and 62-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,31,39,40 and 65-72 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/6/2009</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

Claims 1-3, 8, 31, 39-52, and 62-72 are pending. Claims 41-52 and 62-64 are withdrawn from consideration as nonelected subject matter. Claims 1 and 65 are amended by the amendment filed 2/6/2009. Claims 1-3, 8, 31, 39, 40, and 65-72 are under consideration.

Withdrawn Rejections

The rejection of claims 1-3, 5-8, 31, 39, 40, and 65-72, under 35 U.S.C. 102(b) as being anticipated by Seidel et al (WO 99/33956 pub date:7/8/1999; of record in IDS), as set forth in the Office Action, mailed 2/26/2007 on pages 9-10, is withdrawn.

The rejection of claims 1-3, 8, 31, 39, 40, and 65-72, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as set forth in the Office Action, mailed 8/8/2008 (pp. 4-6), is withdrawn.

The rejection of claims 1 and 65, rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, as set forth in the Office Action, mailed 8/8/2008 (p. 7), is withdrawn.

The rejection of claims 1-3, 8, 31, 39, 40, and 65-72, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention in the recitation of “between at least two different fluid stream pressures”, as set forth in the Office Action, mailed 8/8/2008, (p. 6), is withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The amendments to the claims necessitate the following rejection:

Written Description/New Matter

Claims 1-3, 8, 31, 39, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 recites, "altering flow characteristics of said fluid stream to adjust fluid stream pressure to 30 psi and 40 psi". The breadth of this recitation encompasses using at least two different fluid stream pressures for sorting a sperm cell sample. However, the specification does not convey that applicant had ever contemplated such a delivery. Applicant cannot possess that which they have not contemplated.

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MPEP 2163.02 states:

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). The subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

The present specification provides no such reasonable clarity to those skilled in the art that Applicant was in possession of the claimed invention. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. Applicant, therefore, has not reasonably conveyed this concept through the disclosure at the time of filing, and thus the amendment to claim 1 and the

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newly added claim 65 lack adequate written description. Applicant must either show support for the amendment in the specification or cancel the amendment.

Claims 2, 3, 8, 31, 39, and 40 depend upon claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8, 31, 39, 40, and 65-72, as amended or previously presented, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the Office Action, mailed 8/8/2008 (p. 6).

Amended claim 1 and 65 still recite, "viability" and "cleavage rate". These recitations are indefinite because it is unclear to what "viability" and "cleavage rate" are referring.

Applicant's arguments filed 2/6/2009 have been fully considered but they are not persuasive. Applicant traverses this rejection on the grounds that an artisan would understand what is meant "viability" and "cleavage rate". Applicant's arguments are not persuasive because it is unclear to what "viability" and "cleavage rate" is referring. Amending the claims to specify what is viable and what is undergoing cleavage would be remedial.

Claims 2, 3, 8, 31, 39, 40, and 66-72 depend upon claims 1 and 65.

The amendments to the claims necessitate the following new rejection:

Claims 1-3, 8, 31, 39, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites, "altering flow characteristics of said fluid stream pressure to 30 psi and 40 psi". The claims further specify situation wherein the pressure is 30 psi or 40 psi. The metes and bound of this recitation are indefinite because it is unclear if the fluid stream is intended to be 30 psi and 40 psi at the same time or if the fluid stream is intended to be 30 psi or 40 psi, depending on the fertility characteristic being considered.

Claims 2-3, 8, 31, 39, 40, and 62 depend upon claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The amendments to the claims encompass necessitate the re-instatement of the following rejection:

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Claims 1-3, 8, 33, and 65-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS).

In the Office Action mailed, 8/8/2008 (p. 2), this rejection was withdrawn because the claims encompassed "adjust the fluid stream pressure between at least two different fluid stream pressures". Amended claims 1 now recites adjust the fluid stream pressure to 30 psi and 40 psi....wherein said fluid stream pressure is adjusted to a pressure selected from the group consisting of ...40 psi when motility is selected...40 psi when viability is selected...40 psi when cleavage rate is selected" As discussed above, it is unclear if the claim is intended to encompass "30 psi and 40 psi" or "30 psi or 40 psi". The remarks state, "The claims have been clarified to include inter alia, "altering flow characteristics of said fluid stream pressure to 30 psi or 40 psi" (p. 10, par 3, line 1 of remark). Therefore, it seems that Applicant at least intended for the claims to be interpreted as "30 psi or 40 psi". Therefore, the claim 65 is being given this interpretation for art purposes. Thus, amended claims 1 and no longer require the limitations of two different fluid stream pressures and can encompass 30 psi or 40 psi.

Rath et al discloses a method of sorting sperm by sex and determining its ability to generate embryos by in vitro fertilization. Their method is comprised of collecting sperm from boars (p. 3347, col 2, par 1, line 1-2), subjecting the sperm to flow cytometry, and determining the generation of embryos produced by in vitro fertilization (a measure of fertility characteristics) with sex sorted sperm or unsorted sperm (p. 3348 in total). The flow cytometry consisted of generating a

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flow and entraining sperm samples into the fluid stream (p. 3348, col 1). They disclose that the fluid sheath was PBS (p. 3348, col 1). They disclosed that they adjusted the fluid stream flow through the adjustment of pressure to using high-speed sperm sorting with a fluid sheath pressure of 2.81 kg/cm², which is approximately 40 psi, to improve sorting and fertility characteristics over standard speed sorting (p. 3346, col 2, lines 3-7 and p. 3348, col 1). They disclosed that sperm motility following sorting was 60% in all cases (p. 3349, col 1). They also disclose fertilization rates and cleavage rates, which also indicates that the sperm is viable and can serve as a measure of sperm viability as claimed.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

Marcia S. Noble
AU 1632